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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,568	08/31/2000	Mary K. Danks	SJ-0011	7464

31949 7590 05/21/2002

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/21/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/622,568

Applicant(s)
Danks et al.

Examiner
Rebecca Prouty

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1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 1, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-31 is/are pending in the application.
- 4a) Of the above, claim(s) 24, 26, 30, and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 25, and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 6) ☐ Other:

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Claims 1-22 have been canceled. Claims 23-31 are at issue and are present for examination.

Applicant's election with traverse of Group I, Claims 23, 25, and 27-29 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the claims have unity of invention as they all contain the components for use in the same endpoint, namely activation of a prodrug due to the administration of carboxylesterase. This is not found persuasive because this endpoint does not constitute a special technical feature as defined by PCT Rule 13.2 as the prior art clearly teaches methods of using carboxylesterase to metabolize a chemotherapeutic drug to the active drug (see for example Danks et al. or Senter et al.).

The requirement is still deemed proper and is therefore made FINAL.

Claims 24, 26, 30-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Claim 27 is objected to as including non-elected subject matter.

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Claim 25 is objected to because of the following informalities: abbreviations (such as "CPT-11 or APC") should not be used in the claims without reciting the full terminology for which they are used unless they are common within the art. Appropriate correction is required.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 is confusing in the recitation of "prodrug comprises CPT-11 **and** APC" as CPT-11 and APC are distinct chemical compounds. Did applicants intend "prodrug selected from the group consisting of CPT-11 **and** APC"? This is assumed for purposes of further examination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims s 23, 25, 27 and 28 rejected under 35 U.S.C. 102(b) as being anticipated by Senter et al (Reference AG of Applicant's PTO-1449.

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Senter et al. teach methods of increasing the activation of the prodrugs Paclitaxel and camptothecin (CPT-11) to active drugs in human and mouse tumor cells by the administration of rat serum carboxylesterase following administration of the prodrug.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Senter et al.

Senter et al. is discussed above. They do not teach the administration of the rat serum carboxylesterase prior to the administration of the prodrug. However, as the Senter et al. suggest using the rat serum carboxylesterase for cancer treatment and specifically state that "It may be possible to use rat serum

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carboxylesterase for prodrug activation *in vivo* by targeting the enzyme to tumors with an appropriate monoclonal antibody **and then** administering a prodrug such as PC or CPT-11" (emphasis added) they explicitly suggest the administration of the rat serum carboxylesterase prior to the administration of the prodrug. Furthermore, one of skill in the art would have been motivated to administer the carboxylesterase first in order for it to be targeted to the tumor prior to prodrug administration as this would minimize side effects due to activation of the prodrug in non-tumor cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Rebecca Prouty", with a stylized, cursive script.

Rebecca Prouty
Primary Examiner
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